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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

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May 8, 2012

David P. Holveck
President and Chief Executive Officer
Endo Pharmaceuticals Holdings Inc.
100 Endo Boulevard
Chadds Ford, PA 19317

Dear Mr. Holveck:

As Chairman and a senior member of the Senate Finance Committee, we have a responsibility to the more than 100 million Americans who receive health care under Medicare, Medicaid, and CHIP. As part of that responsibility, this Committee has investigated the marketing practices of pharmaceutical and medical device companies as well as their relationships with physicians and non-profit medical organizations.

It is clear that the United States is suffering from an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers such as Opana and Percocet. According to CDC data, “more than 40% (14,800)” of the “36,500 drug poisoning deaths in 2008” were related to opioid-based prescription painkillers.¹ Deaths from these drugs rose more rapidly, “from about 4,000 to 14,800” between 1999 and 2008, than any other class of drugs,² killing more people than heroin and cocaine combined.³ More people in the United States now die from drugs than car accidents as a result of this new epidemic.⁴ Additionally, the CDC reports that improper “use of prescription painkillers costs health insurers up to \$72.5 billion annually in direct health care costs.”⁵

In Montana, prescription drug abuse is characterized by the state’s Department of Justice as an “invisible epidemic” killing at least 300 people per year and contributing to increases in

¹ Center for Disease Control, “Drug Poisoning Deaths in the United States, 1980-2008, NCHS Data Brief, No. 81, December 2011 at <http://www.cdc.gov/nchs/data/databriefs/db81.pdf>.

² Id.

³ CDC Press Release, “Prescription painkiller overdoses at epidemic levels,” November 1, 2011 at http://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

⁴ LA Times, “Drug deaths now outnumber traffic fatalities in U.S., data show,” September 17, 2011 at <http://articles.latimes.com/2011/sep/17/local/la-me-drugs-epidemic-20110918>.

⁵ International Business Times, “Prescription Painkiller Overdoses Cost Insurers \$72.5 Billion Yearly: CDC,” November 3, 2011 at <http://www.ibtimes.com/articles/242437/20111103/prescription-painkiller-overdoses-cost-insurers-72-5.htm>.

addiction and crime.⁶ The University of Montana Bureau of Business and Economic Research estimated that prescription drug abuse is costing the state \$20 million annually in additional law enforcement, social services, and lost productivity.⁷

In Iowa, “the use of opioid painkillers such as hydrocodone and oxycodone has increased dramatically in the last decade,” according to the Governor’s Office of Drug Control Policy. Annual overdose deaths from opioids “increased more than 1,233% from 3 deaths in 2000 to 40 deaths in 2009.”⁸ Data from Iowa’s prescription drug monitoring program demonstrates that in 2010, 89,500,000 doses of hydrocodone and oxycodone were prescribed totaling nearly 40% of all controlled substance prescriptions.⁹

Concurrent with the growing epidemic, the *New York Times* reports that, based on federal data, “over the last decade, the number of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of their long-term effectiveness or risks” while “[d]ata suggest that hundreds of thousands of patients nationwide may be on potentially dangerous doses.”¹⁰

There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic by promoting misleading information about the drugs’ safety and effectiveness. Recent investigative reporting from the *Milwaukee Journal Sentinel/MedPage Today* and *ProPublica* revealed extensive ties between companies that manufacture and market opioids and non-profit organizations such as the American Pain Foundation, the American Pain Society, the American Academy of Pain Medicine, the Federation of State Medical Boards, and the University of Wisconsin Pain and Policy Study Group.

According to the *Milwaukee Journal Sentinel/MedPage Today*, a “network of national organizations and researchers with financial connections to the makers of narcotic painkillers...helped create a body of dubious information” favoring opioids “that can be found in prescribing guidelines, patient literature, position statements, books and doctor education courses.”¹¹ For example, the *Sentinel* reported that the Federation of State Medical Boards, with financial support from opioid manufacturers, distributed more than 160,000 copies of a model policy book that drew criticism from doctors because “it failed to point out the lack of science supporting the use of opioids for chronic, non cancer pain.”¹²

In a *ProPublica* story published in the *Washington Post*, the watchdog organization examined the American Pain Foundation, a “health advocacy” organization that received “nearly

⁶ See the Montana Department of Justice website at <http://doj.mt.gov/prescriptionabuse/>.

⁷ Bureau of Business and Economic Research, “The Economic Cost of Prescription Drug Abuse in Montana”, June 2011 at <http://mbcc.mt.gov/PlanProj/Projects/PDMP/Prescription%20Drug%20Abuse%2020110629.pdf>.

⁸ Iowa Governor’s Office of Drug Control Policy, “Iowa Drug Control Strategy: 2012,” November 1, 2011 at http://www.iowa.gov/odcp/drug_control_strategy/Strategy2012.Final.pdf

⁹ Id.

¹⁰ NY Times, “Tightening the Lid on Pain Prescriptions,” April 8, 2012 at <http://www.nytimes.com/2012/04/09/health/opioid-painkiller-prescriptions-pose-danger-without-oversight.html>.

¹¹ Milwaukee Journal Sentinel/MedPage Today, “Follow the Money: Pain, Policy, and Profit,” February 19, 2012 at <http://www.medpagetoday.com/Neurology/PainManagement/31256>.

¹² Id.

90 percent of its \$5 million funding from the drug and medical device industry.”¹³ *ProPublica* wrote that its review of the American Pain Foundation’s “guides for patients, journalists, and policymakers play down the risks associated with opioids and exaggerate their benefits. Some of the foundation’s materials on the drugs include statements that are misleading or based on scant or disputed research.”¹⁴

Although it is critical that patients continue to have access to opioids to treat serious pain, pharmaceutical companies and health care organizations must distribute accurate information about these drugs in order to prevent improper use and diversion to drug abusers.

As part of our effort to understand the relationship between opioid manufacturers and non-profit health care organizations, please provide the following information:

1) Provide a detailed account of all payments from 1997 to the present between Endo and the following organizations in table format:

a. Organizations

- i. The American Pain Foundation
- ii. The American Academy of Pain Medicine
- iii. The American Pain Society
- iv. The American Geriatric Society
- v. The Wisconsin Pain and Policy Study Group
- vi. The Alliance of State Pain Initiatives
- vii. The Center for Practical Bioethics
- viii. Beth Israel Medical Center, Department of Pain Medicine and Palliative Care
- ix. The Joint Commission (and all related entities)
- x. The Federation of State Medical Boards

b. Individuals

- i. Russell K. Portenoy, M.D. – Chairman, Department of Pain Medicine And Palliative Care at Beth Israel Medical Center
- ii. Scott M. Fishman, M.D. – Chief, Department of Pain Medicine, University of California, Davis
- iii. Perry G. Fine, M.D. - Professor of Anesthesiology, Pain Research Center, University of Utah School of Medicine
- iv. Lynn R. Webster, M.D., F.A.C.P.M., F.A.S.A.M. – Medical Director and Founder, Lifetree Clinical Research & Pain Clinic
- v. Rollin M. Gallagher, M.D., M.P.H. – Director of Pain Management, Philadelphia Veteran Affairs Medical Center
- vi. Bill McCarber, M.D. – Founder of the Chronic Pain Management Program for Kaiser Permanente in San Diego, CA

¹³ ProPublica, “The Champion of Painkillers,” December 23, 2011 at <http://www.propublica.org/article/the-champion-of-painkillers>.

¹⁴ Id.

- vii. Martin Graboys, M.D. – President, American Academy of Pain Medicine
 - viii. Myra Christopher – Kathleen M. Foley Chair for Pain and Palliative Care, Center for Practical Bioethics
 - c. For each organization or individual identified in 1(a) and 1(b), provide:
 - i. Date of payment.
 - ii. Payment description (CME, royalty, honorarium, research support, etc.).
 - iii. Amount of payment.
 - iv. Year-end or year-to-date payment total and cumulative total payments for each organization or individual.
- 2) All documents and communications from 2004 to the present pertaining to the book, “Responsible Opioid Prescribing: A Physician's Guide,” distributed by the Federation of State Medical Boards.
 - a. Provide the names, titles, and job descriptions of all employees who collaborated with the Federation of State Medical Boards, Dr. Scott Fishman, or third-party contractors on the development of this book.
 - b. For each employee identified in 2(a), provide a summary of the work performed pertaining to the book.
 - 3) All documents and communications from 2007 to the present pertaining to the development or changes to JCAHO’s¹⁵ pain management standards, including but not limited to communications with the American Pain Society and other organizations involved in developing JCAHO pain management standards.
 - 4) All documents and communications from 2007 to the present pertaining to the development or changes to The American Pain Society’s pain guidelines.
 - 5) All documents and communications from 2004 to the present pertaining to the American Pain Foundation’s Military/Veterans Pain Initiative.
 - 6) All documents and communications from 2007 to the present pertaining to any policies, guidelines, press releases and/or position papers distributed by the American Pain Foundation.
 - 7) All presentations, reports, and communications to Endo’s management team or board of directors from 2007 to the present pertaining to the funding of and/or collaborations with of any of the organizations or individuals specified in request 1(a) or 1(b).

¹⁵ All requests pertaining to JCAHO include related organizations such as the “Joint Commission Resources.”

In cooperating with the Committee's review, no documents, records, data, or other information related to these matters, either directly or indirectly, shall be destroyed, modified, removed, or otherwise made inaccessible to the Committee.

We look forward to hearing from you by no later than June 8, 2012. All documents responsive to this request should be sent electronically, on a disc, in searchable PDF format to my staff. If you have any questions, please do not hesitate to contact Christopher Law with Senator Baucus at (202) 224-4515 or Erika Smith with Senator Grassley at (202) 224-5225.

Sincerely,

A handwritten signature in blue ink that reads "Chuck Grassley". The signature is fluid and cursive, with the first name "Chuck" being more prominent.

Charles E. Grassley
Senator

A handwritten signature in blue ink that reads "Max Baucus". The signature is fluid and cursive, with the first name "Max" being more prominent.

Max Baucus
Chairman